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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,358	09/04/2003	Donna L. Robinson	S-100,543	8708
35068	7590	10/26/2005	EXAMINER	
UNIVERSITY OF CALIFORNIA LOS ALAMOS NATIONAL LABORATORY P.O. BOX 1663, MS A187 LOS ALAMOS, NM 87545			FORMAN, BETTY J	
		ART UNIT	PAPER NUMBER	
		1634		

DATE MAILED: 10/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/656,358	ROBINSON, DONNA L.
Examiner	Art Unit	
BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 16 August 2005.
- 2a) This action is **FINAL**.                                   2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-10 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 04 September 2003 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Status of the Claims***

1. This action is in response to papers filed 16 August 2005 in which claims 1 and 5 were amended and the previous rejections were traversed. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 29 November 2004 under 35 U.S.C. 112, second paragraph are withdrawn in view of the amendments. The previous rejections under 35 U.S.C. 112, first paragraph are withdrawn in view Applicant's remarks on pages 5-8 of the response and references cited in the IDS. New grounds for rejection, necessitated by the references submitted with the IDS, are discussed.

Claims 1-10 are under prosecution.

***Specification***

2. The disclosure is objected to because of the following formalities: This application contains color drawings.

Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roche Diagnostics GmbH, "GC-Rich PCR System", July 2001) in view of Landre et al (PCR Stratages, "The use of cosolvents to enhance amplification by the polymerase chain reaction", 1995) and Tabor et al (U.S. Patent No. 5,614,365, issued 25 March 1997).

The claims are drawn to methods of fluorescence-based sequencing comprising a) mixing sample DNA, primers having a Td of about 72-75, a polymerase, dNTPs and ddNTPs and buffer; and performing cycles of b) dissociating at about 92-95 for about 3 minutes; c) annealing at about 65-67 for about 30 seconds; and extending at about 75-78 for about 3-4 minutes to determine the sequence of the sample DNA. Further embodiments define the number of cycles at 30-50, 50-60 or 60-70 using Taq polymerase.

Roche teaches specific examples of sequencing using G-C-rich primers (high Td) wherein they suggest 35 cycles of 3 minutes @ 95/30 seconds @ 65/45 seconds/kb @ 72 (procedure 3.3). They further suggest increasing cycles number to increase product formation (trouble shooting 5.1). While they do not specifically teach extensions at 75, the claims are drawn to temperatures of "about 75". The instant specification does not define the meets and bounds of the term "about". The extension temperatures of Roche clearly suggest the claimed "about 75".

The courts have stated where the claimed ranges "overlap or lie inside the ranges disclose by the prior art" and even when the claimed ranges and prior art ranges do not overlap but are closed enough that one skilled in the art would have expected them to have similar

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properties, a *prima facie* case of obviousness exists (see *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990); *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (see MPEP, 2144.05 I.). Therefore, the claimed ranges

Furthermore, it was known in the art at the time the claimed invention was made that optimal temperature for DNA synthesis using Taq polymerase is 75-80 (Landre et al, first paragraph. Landre et al further teach that use of the higher temperatures for annealing and extension increases specificity, yield and sensitivity of the amplification (page 3, first paragraph). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the temperatures of Roche by using temperatures of about 75-78 as claimed, for the expected benefit of increased specificity, yield and sensitivity of the amplification as taught by Landre et al (page 3, first paragraph).

Roche is silent regarding the reaction mixture containing ddNTPs and mutated Taq. However, Tabor et al teach a similar method wherein ddNTPs are incorporated using the claimed mutated Taq wherein the mutated Taq incorporates the ddNTPs at least 20 fold better than naturally occurring polymerase (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the ddNTP incorporation using F667Y Taq for the expected benefit of 20-fold improved incorporation and sequencing as taught by Tabor (Abstract, Column 12, lines 10-25).

5. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 11 February 2005 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### **Conclusion**

6. No claim is allowed.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions

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daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
BJ Forman, Ph.D.  
Primary Examiner  
Art Unit: 1634  
October 19, 2005